



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

33474d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone 612-334-4100

August 26, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 41

Robert W. Lazarz
Chief Executive Officer
L & L Foods, Inc.
315 Investment Court
Verona, Wisconsin 53593

Dear Mr. Lazarz:

We inspected your firm located at 315 Investment Court, Verona, Wisconsin, on August 5, 2002, and found that you have serious deviations from the Seafood HACCP regulations (Title 21, Code of Federal Regulations, Part 123 [21 CFR 123]). These deviations, some of which were previously brought to your attention, cause your refrigerated seafood salads and seafood dips to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). You can find the Act and the seafood HACCP regulations through links on FDA's home page at www.fda.gov.

The deviations were as follows:

Your firm does not have a HACCP plan for refrigerated seafood salad and seafood dip to control the food safety hazards of pathogen development and temperature abuse. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(b). Additionally, you must maintain critical control monitoring records which are developed to demonstrate control of the causative factors of those hazards, for example, temperature of product at receiving and during storage, 21 CFR 123.6(c)(4). This deviation was previously brought to your attention in our letter of July 9, 2001.

No one within your firm has successfully completed a HACCP training course. You must have record review of monitoring records performed by an adequately trained or qualified individual to comply with 21 CFR 123.10(c).

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We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from distributing seafood products.

Please respond in writing within three weeks of your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response, documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Compliance Officer Tyra S. Wisecup at the address in the letterhead. If you have questions regarding any issue in this letter, please contact Ms. Wisecup at (612) 334-4100 ext. 124.

Sincerely,


James A. Rahto
Director
Minneapolis District

TSW/ccl

